Outcomes Assessment

Chronic Heart Failure

Prepared for Kansas Medical Assistance Program in September, 2004

EXECUTIVE SUMMARY

Purpose of Intervention

The primary purpose of this intervention is to improve the treatment of heart failure (HF) by reducing practice variance through the use of clinical practice guidelines.

Intervention

Intervention Type	Population-based mailing
Intervention Mailing Date	December 2003
Pre-intervention Period (Baseline)	July 2003 – December 2003
Post-intervention Period (Post)	February 2004 – July 2004
Number of Letters Mailed	1,296
Number of Targeted Physicians	1,296
Number of Targeted Patients	4,831
Adjusted Targeted Patients	3,331
Number of Control Physicians	0
Number of Control Patients	0
Adjusted Control Patients	0

Changes in Clinical Indicators

Clinical Indicators	Baseline	Target Jul-04	% Change
Drug-Drug Interactions	101	67	-33.7%
Duplicate Therapy	1	1	0.0%
Underutilization	2,738	2,302	-15.9%
Increased Risk of ADE	530	384	-27.5%
Non-Compliance	53	17	-67.9%

Savings Calculations

Intervention-Related Drug Therapy	
Targeted Group: Actual Average Paid Amount Per Patient Per Month (Baseline)	$33.77
Targeted Group: Actual Average Paid Amount Per Patient Per Month (Post)	$34.63
Estimated Savings Per Patient Per Month	($0.86)
Total Number of Targeted Patients	3,331
6-Month Total Savings	($17,109.44)

Medical Expenditures	
Targeted Group: Actual Average Paid Amount Per Patient Per Month (Baseline)	$1,639.01
Targeted Group: Actual Average Paid Amount Per Patient Per Month (Post)	$1,576.01
Estimated Savings Per Patient Per Month	$63.01
Total Number of Targeted Patients	3,331
6-Month Total Savings	$1,259,285.34

BACKGROUND

Heart failure (HF) affects almost five million Americans and 400,000 to 700,000 new cases are being diagnosed annually. The incidence and prevalence of heart failure continues to rise, despite recent clinical trials showing that certain drugs may reduce the morbidity and mortality associated with heart failure. This trend is expected to continue as the population ages and more patients survive myocardial infarctions.[1] It is the most common cause of hospitalizations in patients greater than 65 years old and accounts for approximately 300,000 deaths per year. It also accounts for a large amount of health care expenditures costing approximately $20 to 40 billion each year, which does not include indirect costs due to lost productivity.[2,3] Nearly two-thirds of the economic burden is attributed to hospitalizations for worsening clinical status.[4]

There are numerous factors, some of which are avoidable, that can precipitate HF exacerbations:[3-7]

Medication Related	Comorbidities	Other
♦ Noncompliance with medications ♦ Use of inappropriate medications: ○ antiarrhythmic agents (except amiodarone) ○ calcium channel blockers (except amlodipine or felodipine) ♦ NSAID use ♦ Underutilization or sub-optimal doses of angiotensin converting enzyme (ACE) Inhibitors ♦ Inappropriate reductions in HF medications	♦ Uncontrolled hypertension ♦ Depression ♦ Myocardial ischemia ♦ Arrhythmias (primarily tachyarrhythmias) ♦ Miscellaneous non-cardiac disorders (e.g., pulmonary infectious processes)	♦ Advanced age ♦ Excessive salt intake ♦ Noncompliance with diet

Beta-blocker use in HF was once thought to be harmful. However, it is now known that the appropriate use of these agents can decrease HF morbidity and mortality.[8-10] The 2001 ACC-AHA HF guidelines recommend these agents for routine use in most patients with HF.

---

[1] Konstam MA, Dracup K, Bottorff MB, et al. Evaluation and care of patients with left-ventricular systolic dysfunction. Clinical practice guideline 11. Washington, DC: Agency for Health Care Policy and Research, U.S. Department of Health and Human Services, June 1994. AHCPR Publication No. 94-0612.

[2] Consensus recommendations for the management of chronic heart failure. Am J Cardiol 1999;83(2A):1A-38A.

[3] Hunt SA, Baker DW, Chin MH, et al. ACC/AHA Guidelines for the Evaluation and Management of Chronic Heart Failure in the Adult. The American College of Cardiology and the American Heart Association, 2001. Available from http://www.acc.org/clinical/guidelines/failure/hf_index.htm.

[4] Tsuyuki RT, McKelvie RS, Arnold MO, et al. Acute precipitants of congestive heart failure exacerbations. Arch Intern Med 2001; 161:2337-2342.

[5] Feenstra J, Heerdink RK, Grobbee DE, Stricker BH. Association of nonsteroidal anti-inflammatory drugs with first occurrence of heart failure and with relapsing heart failure. The Rotterdam Study. Arch Intern Med 2002;162:265-270.

[6] Jiang W, Alexander J, Christopher E, et al. Relationship of depression to increased risk of mortality and rehospitalization on patients with congestive heart failure. Arch Intern Med 2001;161:1849-1856.

[7] Mosterd A, Hoes AW. Reducing hospitalizations for heart failure (editorial). European Heart J 2002;23(11):842-845.

[8] MERIT-HF Study Group. Effect of metoprolol CR/XL in chronic heart failure. Metoprolol CR/XL Randomized Intervention Trial in Congestive Heart Failure (MERIT-HF). Lancet 1999;353:2001-7.

[9] CIBIS-II Investigators and Committees. The Cardiac Insufficiency Bisoprolol Study (CIBIS-II): a randomized trial. Lancet 1999;353:9-13.

[10] Packer M, Coates AJS, Fowler MB, et al. Effect of carvedilol on survival in severe chronic heart failure. N Engl J Med 2001;344(22):1651-1658.

METHODOLOGY

Changes in intervention-related pharmacy dollars paid, pharmacy dollars paid per patient per month (PPPM), number of pharmacy claims, and intervention-related medical utilization were examined. This intervention identified providers whose patients were affected by potential drug-drug interactions, duplicate therapy, underutilization of therapy, increased risk of adverse drug events, or non-compliance with drug therapy. To assess the impact of the intervention, pharmacy drug claims were reviewed from February 2004 through July 2004.

Clinical Criteria: Criteria, rationale, and text message(s) to providers are listed below. All physicians with at least one recipient "hitting" on criteria received letters.

- Drug-Drug Interaction
  This indicator identifies patients with drug-drug interactions classified as moderate to severe for at least 7 days in a 45-day period of time.

  Rationale: Patients with potential drug-drug interactions are at increased risk of having an adverse drug event. There may be coordination of care issues if more than one prescriber is involved.

  Sample Provider Paragraph:

  > Digoxin-verapamil interaction involving >1 prescriber: Verapamil may increase the effect of digoxin. Please monitor serum digoxin concentrations, especially when changes in verapamil therapy occur.

- Duplicate Therapy
  This measure looks at patients taking either multiple cardiac glycosides or multiple ACE modulating agents with at least a 35 day overlap in therapy in a 60 day period.

  Rationale: Duplicate ACE-modulating and duplicate cardiac glycoside therapy have an increased risk of adverse drug events without a corresponding increase in efficacy.

  Sample Provider Paragraph:

  > Potential therapeutic duplication: Concurrent use of more than one angiotensin modifying agent. Please review the need for this combination of medications and, if you have not already done so, verify that your patient has discontinued the appropriate agent(s).

- Underutilization
  The underutilization of therapy indicator identifies patients underutilizing beta-blockers or ACE inhibitors in the past 90 days.

  Rationale: Beta blocker use (i.e., carvedilol, metoprolol, bisoprolol) in conjunction with an angiotensin modulating agent (e.g., ACE inhibitor or angiotensin II receptor antagonist) substantially decreases morbidity and mortality in patients with HF. Current practice guidelines recommend the use of beta blockers in all patients with stable HF due to left ventricular dysfunction, unless the use of these medications is contraindicated or is not tolerated. Contraindications include reactive airway disease, unstable fluid status, and symptomatic bradycardia or advanced heart block without a pacemaker.

Sample Provider Paragraph:

> Potential underutilization: Diagnosis of heart failure (HF) without ACE inhibitor. National guidelines support the use of ACE inhibitor therapy (in the absence of contraindications) in all patients with HF secondary to left ventricular dysfunction. For most patients with HF, ACE inhibitor therapy is beneficial and may reduce morbidity and mortality. Please review this patient's current therapy and determine if use of an ACE inhibitor would be appropriate for this patient.

- Increased Risk of Adverse Drug Events

  The increased risk of adverse drug event indicator identifies patients receiving medications who are at risk of experiencing an adverse drug event due to predisposing medical conditions. Additionally, certain concomitant medication therapy may result in additive effects resulting in adverse events.

  Rationale: Medication related adverse events are common in primary care, and many are preventable or ameliorable. Improvements in monitoring for and responding to symptoms are especially important for the prevention of adverse drug events in outpatients.

  Sample Provider Paragraph:

  > Increased risk of adverse effect: Metformin-Containing Product(s) with Heart Failure DX. According to pharmacy and medical claims data, it appears that your patient has a diagnosis of heart failure (HF) and received a metformin-containing product. Metformin should not be used in patients with acute or unstable HF requiring drug therapy due to the risk of hypoperfusion and hypoxemia, which may lead to lactic acidosis. Please review the need for this medication, consider the use of appropriate alternatives, or regularly monitor for clinical signs and symptoms of lactic acidosis or worsening of renal function and exacerbation of HF.

- Medication Non-Compliance

  Patients receiving digoxin or antihypertensive medication who received less than 60 days supply of the drug during a 90-day period of time.

  Rationale: Noncompliance with prescribed regimens is a major cause of hospitalizations. Studies have shown that noncompliance with diet or medications is a common reason for HF exacerbations which lead to hospital readmissions.[2]

  Sample Provider Paragraph:

  > Your patient may be non-compliant with the identified chronic cardiovascular drug therapy. From prescription data, it appears that your patient received <60 days of maintenance therapy in a 90 day period. Please review this information to determine the best course of action for your patient.

Definitions:

Adjusted Target Patients – All patients of physicians who were included in the intervention, who had pharmacy claims and were active plan members throughout the post-intervention time period. Additionally, when outcomes are performed, these patients' pre-intervention (baseline) hits are re-evaluated to make certain that the status of clinical indicators haven't changed for each patient due to late pharmacy and medical claims.

Intervention-Related Drugs – selective COX-2 inhibitors and nonselective NSAIDs.

Characteristics

Table 1 describes the patient population included in the population-based intervention based upon mean age, gender, number of providers, average number of prescriptions per patient per month, and utilization of intervention-related drugs at baseline. As can be seen from the table, the target group had about three times as many females as males, were seeing 2.7 providers, receiving 9.0 prescriptions per month, and taking an average of 1.9 intervention-related drugs.

Table 1: Patient Characteristics

	Target (N=3,331)
Mean Age	**73.4**
Percentage Male	**26.1%**
Percentage Female	**73.9%**
Number of Providers	**2.7**
Average Number of Prescriptions PPPM*	**9.0**
Utilization of Intervention-Related Drugs**	
Average Number of Drugs***	**1.9**
Average Number of Claims	**8.9**
Average Days Supply	**254.5**
Average Amount Paid	**$202.62**

* Number of prescriptions per patient per month (PPPM) is the average for the 6 month baseline period

** Based on 6 months of baseline claims data

*** A distinct drug is defined by using a coding system similar to the Hierarchical Ingredient Code List (HICL) in that distinct drugs are identified at the ingredient level.

Drug-Drug Interactions

Table 2 exhibits the incidence of patients identified as being at risk for potential drug-drug interactions. The intervention saw sizable reductions in most of the indicators. Overall, a reduction in drug-drug interaction clinical indicators of 33.7% was achieved during the post-intervention period.

Table 2: Changes in Drug-Drug Interactions

Drug-Drug Interactions	Target		
	Baseline	Jul-04	% Change
Digoxin-Verapamil, >1 MD	3	2	-33.3%
Digoxin-Spironolactone, >1 MD	12	5	-58.3%
Digoxin-Diltiazem, >1 MD	13	10	-23.1%
Digoxin-Carvedilol, >1 MD	25	16	-36.0%
Digoxin-Quinidine, >1 MD	2	2	0.0%
Metoprolol-Amiodarone	25	17	-32.0%
Metoprolol-Ciprofloxacin	4	1	-75.0%
Metoprolol-Diazepam	2	1	-50.0%
Metoprolol-Diphenhydramine	8	7	-12.5%
Metoprolol-Quinidine	1	1	0.0%
Carvedilol-Diphenhydramine	2	2	0.0%
Digoxin-Amiodarone, >1 MD	3	2	-33.3%
Digoxin-Propafenone, >1 MD	1	1	0.0%
Total	101	67	-33.7%

Duplicate Therapy

The change in the incidence of patients identified as being on duplicate therapy is displayed in Table 3. The single patient that was identified at baseline as receiving duplicate therapy was still receiving duplicate therapy in the post-intervention period.

Table 3: Changes in Duplicate Therapy

Duplicate Therapy	Target		
	Baseline	Jul-04	% Change
ACEI & Related Drugs >1 MD	1	1	0.0%

Underutilization

Table 4 exhibits the incidence of patients identified as underutilizing beta-blocker or ACE inhibitor therapy. Overall, a reduction in underutilization clinical indicators of 15.9% was achieved during the post-intervention period.

Table 4: Changes in Underutilization

Underutilization	Target		
	Baseline	Jul-04	% Change
CHF Diagnosis: No ACEI	427	321	-24.8%
ACE-Subtarget dose (CHF DX)	112	82	-26.8%
Beta-blocker in HF	1,932	1,688	-12.6%
CHF, Inferred: No ACEI	267	211	-21.0%
Total	2,738	2,302	-15.9%

Increased Risk of ADE

The change in the number of patients identified as being at an increased risk of ADE is presented in Table 5. Overall, a reduction in the increased risk of ADE clinical indicators of 27.5% was achieved during the post-intervention period.

Table 5: Changes in Risk of ADE

Increased Risk of ADE	Target		
	Baseline	Jul-04	% Change
Metformin-Containing Product(s) with Heart Failure	177	133	-24.9%
Beta Blocker use w/ 2nd or 3rd degree AV block	5	3	-40.0%
NSAID use with CHF dx	15	10	-33.3%
Digoxin & CRF	55	40	-27.3%
>0.125 mg/d Dig, >= 70 yo	38	26	-31.6%
Potential Drug-Disease Interaction: Itraconazole with HF	1	0	-100.0%
Thiazolidinediones & HF DX	239	172	-28.0%
Total	530	384	-27.5%

Non-Compliance

Table 6 exhibits the changes in the number of patients identified as being non-compliant with their drug therapy. The intervention saw sizable reductions in each of the indicators. Overall, a reduction in non-compliance clinical indicators of 67.9% was achieved during the post-intervention period.

Table 6: Changes in Non-Compliance

Non-Compliance	Target		
	Baseline	Jul-04	% Change
Cardiovascular med, no HTN dx	3	2	-33.3%
Digoxin	33	10	-69.7%
HTN med & dx = HTN	17	5	-70.6%
Total	53	17	-67.9%

BUSINESS ANALYSIS

The overall savings for the intervention are calculated in Tables 7 and 8. Per patient per month (PPPM) drug amount paid for intervention-related drugs and medical claims were separately calculated for the target group for the six-month baseline and six-month post-intervention periods. The post-period PPPM amount paid for the target group was subtracted from the baseline PPPM amount paid to obtain the estimated PPPM savings. The PPPM savings was then multiplied by the number of intervention months and number of target patients.

As would be expected from the decrease in underutilization and the large increase in compliance seen in the clinical analysis, Table 7 shows the amount paid for intervention-related drugs increased $0.86 in the post-intervention period. This yielded an overall increase of $17,109 in intervention-related drug expenditures during the six-month post-intervention period.

As seen in Table 8, as a result of the intervention, the estimated per patient per month savings for intervention-related medical claims was $63.01. This yields an overall medical savings of $1,259,285 during the six-month post-intervention period.

Table 7: Intervention-Related Drug Savings

Savings Calculation:	
Targeted Group: Actual Average Paid Amount Per Patient Per Month (Baseline)	$33.77
Targeted Group: Actual Average Paid Amount Per Patient Per Month (Post)	$34.63
% Change in Target Group from Baseline to Post	2.53%
Estimated Savings Per Patient Per Month	($0.86)
Total Number of Targeted Patients	3,331
6-Month Total Savings	($17,109.44)

Table 8: Intervention-Related Medical Savings

Savings Calculation:	
Targeted Group: Actual Average Paid Amount Per Patient Per Month (Baseline)	$1,639.01
Targeted Group: Actual Average Paid Amount Per Patient Per Month (Post)	$1,576.01
% Change in Target Group from Baseline to Post	-3.84%
Estimated Savings Per Patient Per Month	$63.01
Total Number of Targeted Patients	3,331
6-Month Total Savings	$1,259,285.34

LIMITATIONS

A control group was not utilized for this intervention. This limited the comparisons that could be performed in the analysis. Therefore, instead of being able to compare an intervention group with a non-intervention group, the analysis is essentially limited to changes in the intervention group before and after intervention.

The time frame of 6 months may not capture the full extent of the impact of the chronic heart failure intervention. Providers may be required some time before they can change their patient's drug regimens.

CONCLUSIONS

This chronic heart failure intervention focused on improving prescribing practices and reducing the overall cost of care. The intervention was successful in reducing the target patients flagged for underutilizing beta-blocker therapy by 29.5%.

As would be expected from the large increase in compliance and the decrease in underutilization seen in the clinical analysis, the amount paid for intervention-related drugs increased $0.86 in the post-intervention period. This yielded an overall increase of $17,109 in intervention-related drug expenditures during the six-month post-intervention period. However, as a result of the intervention, the estimated paid amount per patient per month for intervention-related medical claims decreased $63.01. This yields an overall intervention-related medical savings of $1,259,285 during the six-month post-intervention period. Therefore, the total savings due to the intervention was $1,242,176 during the six-month post-intervention period.